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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,947	09/10/1998	RAYMOND KAEMPFER	A31967-PCT-U	7084

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/150,947	Applicant(s) KAEMPFER ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-99 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50-99 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicants amendment filed February 13, 2004 has been received and entered. New claims 94-99 have been added, accordingly claims 50-99 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 88-93 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Additionally this rejection is applied to newly added claims 94-99.

Applicants are asserting that what is conventional or well known to one of skill in the art need not be disclosed in detail. *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 802 F2d at 1384, 231, USPQ at 94. Applicants further assert that one of skill in the art would easily detect the consensus sequences of the present invention and recognize that the inventors were in possession of the claimed invention. Applicants further assert that it would be readily apparent to one of skill in the art that such sequences share the common motif as shown in Tables 1 and 4.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that what is conventional or well known to one of skill in the art need not be disclosed in detail. However, it does not follow that a few examples of

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particular sequences provides support for other sequences of undefined structure. One of skill in the art would not readily recognize a genus of sequences based upon a couple of examples without some guidance as to which particular sequences are important for activity. Without such a statement in the specification, the attempt to claim new sequences based upon parts of already disclosed sequences is simply adding to the scope of the claimed invention. Applicants further assert that it would be readily apparent to one of skill in the art that such sequences share the common motif as shown in Tables 1 and 4. However, without a statement or some guidance to direct one of skill in the art to select any protein having rudimentary identity to the claimed sequences, the attempt to claim proteins of expanded scope is deemed new matter.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 65-75 and 88-93 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained. Additionally this rejection is applied to newly added claims 94-99.

Applicants are asserting that SEQ ID NO: 1-11 are clearly set forth in the specification and the consensus sequences derived therefrom (SEQ ID NO: 13-18), as would be clearly apparent to one of skill in the art. Applicants further assert that the

group of sequences having KKK and QELD equally spaced apart, share toxin antagonist activity. Applicants conclude that one of skill in the art would view this disclosure as sufficient in presenting the number of representative species and the function shared by members of the genus.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants written description of SEQ ID NO: 1-11 is not being questioned, indeed fragments "consisting of" SEQ ID NO: 1-11 all meet the requirements of written description. However, as set forth previously, the genus is highly variant, SEQ ID NO: 1-11, alone, which are fragments of full length proteins are insufficient to describe the genus. Furthermore, Applicants assert that the KKK and QELD motifs, features shared by peptides p12 and pSEB are spaced equally in both and **may** be important for antagonist activity. (Specification page 25) (Emphasis added). However, Applicants function has been drawn from two sequences and is a mere assertion that these fragments of the sequence "may" be responsible for antagonist activity.

Finally, Applicants conclude that one of skill in the art would view this disclosure as sufficient in presenting the number of representative species and the function shared by members of the genus. However, as set forth above, Applicants have only based a presumption of activity on a fragment of a protein compared between two sequences (p12 and pSEB). This simply does not rise to the level of providing support for a genus of claims "comprising" fragments of a protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 76, 90 and 93 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 50-65, 68, and 76-87 under 35 U.S.C. 102(b) as being anticipated by Tice et al is maintained.

Applicants are asserting that in contrast to the present invention, the full length SEB protein taught by Tice et al has been treated with formalin to produce a toxoid, which is then encapsulated. Applicants assert that the toxoid is thus denatured and would not retain the conformation of the domain from which the peptides of the

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invention are derived, i.e. the central turn in the toxin molecule starting within the β strand 8, to α helix 4, and ending within α helix 4. Applicants further assert that Tice fails to disclose a peptide that is capable of antagonizing toxin mediated T lymphocyte activation.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that in contrast to the present invention, the full length SEB protein taught by Tice et al has been treated with formalin to produce a toxoid, and that the toxoid is denatured and would not retain the conformation of the domain from which the peptides of the invention are derived, i.e. the central turn in the toxin molecule starting within the β strand 8, to α helix 4, and ending within α helix 4. However, Applicants are respectfully directed back to the claims. The claims recite "An isolated and purified peptide having an amino acid sequence ***homologous to an amino acid sequence*** of a domain of a pyrogenic exotoxin which domain forms a central turn in the exotoxin... (Emphasis added). In other words, the claimed peptide only needs to be similar (homologous) to one which has the recited limitations. Given that the primary amino acid sequences of the SEB disclosed by Tice et al and the SEB of the instant invention are identical this limitation has been met.

Finally, Applicants assert that Tice fails to disclose a peptide that is capable of antagonizing toxin mediated T lymphocyte activation. However, given that the chemical structure of the molecule disclosed by Tice fully meets each and every limitation of the

claims, the property of being able to antagonizing toxin mediated T lymphocyte activation is deemed to be an inherent property of the protein.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

5. The rejection of claims 89-90, and 92-93 under 35 U.S.C. 102(b) as being anticipated by Ratti et al is maintained. Additionally this rejection is applied to newly added claims 95-96, and 98-99.

Applicants are asserting that Ratti et al do not mention any sequence or peptide isolated that is capable of inhibiting SEB or other toxins.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Ratti et al. Ratti et al disclose of a peptide which is structurally 100% identical to the claimed peptides (SEQ ID NO: 14 or 17) of the instant invention. Given that the peptides are structurally identical, any activity such as capable of inhibiting SEB, is deemed to be an inherent property imparted from the structure of the molecule.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

6. The rejection of claim 88 under 35 U.S.C. 102(b) as being anticipated by Galinski et al is maintained. Additionally this rejection is applied to newly added claim 94.

Applicants are asserting that Galinski et al do not mention any sequence or peptide isolated that is capable of antagonizing toxin mediated activation of T lymphocytes.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Galinski et al. Galinski et al disclose of a peptide which is structurally 100% identical to the claimed peptide (SEQ ID NO: 13) of the instant invention. Given that the peptides are structurally identical, any activity such as capable of antagonizing toxin mediated activation of T lymphocytes, is deemed to be an inherent property imparted from the structure of the molecule.

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Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

7. The rejection of claim 91 under 35 U.S.C. 102(b) as being anticipated by Spriggs et al is maintained. Additionally this rejection is applied to newly added claim 97.

Applicants are asserting that Spriggs et al do not mention any sequence or peptide isolated that is capable of antagonizing toxin mediated activation of T lymphocytes.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the disclosure of Spriggs et al. Spriggs et al disclose of a peptide which is structurally 100% identical to the claimed peptide (SEQ ID NO: 16) of the instant invention. Given that the peptides are structurally identical, any activity such as capable of antagonizing toxin mediated activation of T lymphocytes, is deemed to be an inherent property imparted from the structure of the molecule.

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Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

The following new grounds of rejection are applied:

8. The amendment filed February 13, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "incorporated by reference." While Applicants are entitled to claim priority to the parent applications, any incorporation by reference must be done at the time the application is filed. Attempts to incorporate by reference after the filing date are deemed new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
May 17, 2004